IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***WAVE 1 CASES***	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE TESTIMONY OF BRIAN RAYBON, M.D.

COME NOW, Plaintiffs in the above-referenced action, and file their Response in Opposition to Defendants' motion seeking to exclude testimony of Brian Raybon, M.D. and show as follows:

Statement of Factual and Procedural Background

Dr. Raybon is a fellowship-trained, Board-certified specialist in female pelvic medicine and reconstructive surgery.[1] Dr. Raybon also holds dual degrees in Chemistry and Chemical Engineering from North Carolina State University. Dr. Raybon is a Clinical Assistant Professor at the Medical College of Georgia, and he is helping to develop the first new residency program in the State of Georgia in over two decades. Dr. Raybon has consulted with and worked as a proctor and preceptor for several different mesh manufacturers regarding their pelvic repair mesh devices, and he served as a Site Principal Investigator for two pelvic mesh products sold by American Medical Systems, the TOPAS sling and the Elevate POP repair system. (*See*, Raybon Prolift Report, pp. 1-2 attached to Defendants' motion (Dkt. No. 2115-3)).

[1] A copy of Dr. Raybon's Curriculum Vitae, and a list of his Review Materials served with his Expert Reports, are attached hereto as **Exhibit 1** and **Exhibit 2**, respectively.

Dr. Raybon has implanted and removed numerous pelvic organ prolapse repair mesh products, and more specifically, he has implanted and removed the Prolift product in his patients. (Raybon Prolift Report, pp. 1-2; Raybon depo., 56:4-60:4; 67:20-70:5). Dr. Raybon never used the Prolift +M device because at the time it was marketed, he had stopped using mesh kits for POP repair. (Raybon depo., 73:21-74:21).[2]

Dr. Raybon's credentials and qualifications were addressed in *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *14 (S.D.W.Va.2015) ("Dr. Raybon has extensive experience with POP and the use of mesh as a form of treatment."); *Id.*, p. 15 ("because Dr. Raybon has undeniable experience on this subject matter and has substantiated his opinion with testable, peer-reviewed literature, I must open the gates to his testimony.").

Argument and Citation of Authority

I. Defendants' narrowly limited challenge to Dr. Raybon's general causation opinion regarding nerve damage (and nothing else) should be denied.

Defendants' *Daubert* challenge to Dr. Raybon's general causation opinion focuses exclusively on his opinion regarding the general propensity of the Prolift and Prolift+M to cause "nerve damage," basing their argument almost entirely on the Court's *Daubert* opinion in the *Eghnayem* Boston Scientific Pinnacle consolidation.[3] Dr. Raybon was identified as a specific causation expert in one of the four *Eghayem* consolidation cases. The Court concluded there that

[2] A copy of Dr. Raybon's miniscript deposition is attached hereto as **Exhibit 3**.

[3] Contrary to Defendants' self-serving mischaracterization, Dr. Raybon's general causation opinions are not by any means limited to the general propensity of the Prolift and Prolift +M to cause "nerve damage." Nerve damage is just one of numerous complications generally associated with these devices listed in the "General Causation Opinions" of Dr. Raybon's Report, including pain; inflammation; excessive scar plate formation, banding, and contracture of the arms, resulting in assymetrical pulling on the central portion of the mesh; erosion/exposure; pudendal neuralgia; pelvic muscle spasms; dyspareunia; incontinence; retention; constipation or fecal incontinence; deformed mesh; encapsulation of mesh; vaginal or pelvic deformation; infection; and recurrence. (Raybon Prolift Report, pp. 22-23; Raybon Prolift +M Report, pp. 16-17). Defendants do not specifically address any of the other general causation opinions in their motion or brief; Defendants should be held to have conceded Dr. Raybon's ability to opine as to these complications.

Dr. Raybon was not qualified "to opine on the cause of nerve trauma in the pelvis," and that such opinion was not reliable because he failed to reference any articles or testing that would support such opinion. *Eghnayem v. Boston Scientific Corp.*, 57 F.Supp.3d 658, 700-01 (S.D.W.Va.2014). What Defendants ignore is that, unlike in *Eghnayem*, Dr. Raybon's opinions regarding nerve damage here are based not only on his knowledge, education, training and experience, but also on his review and familiarity with published literature addressing the association between polypropylene mesh implants and nerve damage, as well as several of Defendants' own internal documents – spanning several years – that expressly acknowledge the causal association between synthetic pelvic mesh implants and nerve injury. (*See, e.g.*, Raybon Prolift Report, p. 9 ¶ 6 and footnote 9; p. 17 ¶ 11 and footnote 28; *Id.*, pp. 22-23 and footnote 50).[4] *See also*, Raybon

[4] The following documents and literature are cited in Dr. Raybon's Reports: ETH.MESH.05631478 (8/16/02 internal Ethicon e-mail discussing article describing mesh-related nerve injury – ("In the post retrieval study most explants of all patients with chronic pain in their history indicate nerve fibres and fascicles in the interface of the mesh. Today, immunohistochemical stains relieve even the detection of smallest nerve structures which are mainly found in the foreign body granuloma. Due to the nature of the granuloma as a chronic inflammation it may be speculated that these nerve structures are irritated by the inflammation and cause the sensation of pain"); ETH.MESH.05455879 (1/18/03 notes from Ethicon Surgeon Panel Meeting) – "Nerve entrapment with chronic pain - Persistent chronic pain from foreign body reaction – greater fibrosis greater complaints – Scar plate with nerve entrapment – sometimes after one year there are no complaints and then complaints happen – often the result of tiny nerves in the granuloma not just a matter of not damaging the major nerves such as N ilioinguinalis or R genitalis - even if you care for the big nerves you can't prevent pain."); ETH.MESH.00870466 (6/20/06 notes re: Ethicon Expert Meeting) – "Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve)…. Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option"); HMESH_ETH_01800994 (10/11/06 internal Ethicon e-mail chain discussing mesh pain/shrinkage literature) ("The take home message from the article was that chronic pain can be associated with placement of a mesh device…. [The author] continues to point out that neuropathy-related complaints after intraoperative damage of nerve fibers is associated with pain immediately after surgery, however, the onset of chronic pain as a consequence of the 'foreign body reaction' is typically more than one year after the hernia repair. He goes on to point out that patients that reported chronic pain demonstrated nerve fibers and fascicles in the interface of the mesh upon examination upon removal."); HMESH_ETH_00144721 (2/11/08 internal e-mail) – "Peripheral nerve irritation following synthetic mesh implantation can be implant-related or procedure-related. Implant-related factors include foreign body tissue reaction, fibrotic tissue response and shrinkage."); ETH.MESH.13375497 (10/1/08 internal PowerPoint) (Regarding mesh-related pain "The tissue reaction at the mesh implant is like a chronic wound, present for years and years after the implantation," and studies of explanted meshes show "Nerve fibers and fascicles in the interface of the mesh…The nerve structures are irritated by the inflammation an cause sensation of pain."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the

Review Materials, served with his Expert Reports, copy attached hereto as **Exhibit 2**).[5] *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *15 (S.D.W.Va.2015) ("[T]hough an expert may not simply narrate corporate documents in front of the jury, he may rely on such information in forming and supporting his opinions…For the most part, Dr. Raybon has properly used Bard's internal documents to develop and reinforce his opinions rather than to narrate Bard's corporate conduct."). The same is true here. Given that Defendants' own internal documents have acknowledged and discussed the direct causal link between pelvic mesh implants and nerve

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most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "Studies of explanted meshes: • Nerve fibers and fascicles in the interface of mesh • The nerve structures are irritated by the inflammation and cause sensation of pain [citing 2005 article]."); Smith T, et al., Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center. Female Pelvic Med Reconstr Surg 2013; 19:238-41; Klosterhalfen, et al., The Lightweight and Large Porous Mesh Concept for Hernia Repair. Expert Rev. Med. Devices 2(1) 2005; Castellanas ME et al., Pudendal Neuralgia After Posterior Vaginal Wall Repair with Mesh Kits: An Anatomical Study and Case Series. Journ Minimally Invasive Gynecol 19 (2012) S72; Hansen, B., et al., Long-Term Follow-up of Treatment for Synthetic Mesh Complications, Female Pelvic Med & Reconstr Surg 2014, 20:126-130; Barski D, et al., Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair. Surg Technol Int. 2014, 24:217-24.; Shah, et. al., Mesh complications in female pelvic floor repair surgery and their management: A systematic review. Indian J Urol. 2012 Apr; 28(2):129-53; Feiner, B., et al., Vaginal Mesh Contraction: Definition, Clinical Presentation and Management, Obstet Gynecol 2010, 115:325-330; Morrisoe, S., et al., The use of mesh in vaginal prolapse repair: do the benefits justify the risks? Current Opinion in Urology 2010, 20:275-279; Blandon, et al., Complications from vaginally placed mesh in pelvic reconstructive surgery, Int Urogynecol J 2009, 20:523-31; Jacquetin, B, Complications of Vaginal Mesh: Our Experience, Int Urogyn J, 2009, 20:893-6.

[5] Dr. Raybon's Review Materials include hundreds of internal Ethicon documents related to the Prolift and Ethicon pelvic mesh products generally, as well as dozens of peer-reviewed, published articles specific to the Prolift product. In addition to the articles and internal documents directly referenced in his Report, several of these articles in his Review Materials discuss mesh-related nerve injury, including: Achtari C, et al. Anatomical study of the obturator foramen and dorsal nerve of the clitoris and their relationship to minimally invasive slings. Int Urogynecol J Pelvic Floor Dysfunct. 2006;17(4):330-4; Atassi Z, et al., Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review. Arch Gynecol Obstet. 2008;277(2):161-4; Yi J, Pudendal nerve entrapment following posterior trans-vaginal mesh procedure cadaveric demonstration of pudendal nerve dissection. Pelv Med Reconstr Surg. 2012;18(8):S95. Video 16 at AUGS 2012; Masata J, et al., Pudendal neuralgia following transobturator inside-out tape procedure (TVT-O)--case report and anatomical study. Int Urogynecol J. 2012; 23(4):505-7.

damage for years (including well before the Prolift devices were ever marketed), Defendants' challenge here to Dr. Raybon's opinions regarding this issue is ill-founded.

Furthermore, Defendants disregard the fact that Dr. Raybon was allowed to offer general causation opinion testimony over a defense *Daubert* challenge in the *Wise v. C.R. Bard, Inc.* trial selection case in the Bard MDL. In *Wise*, Bard asserted an argument seeking to exclude Dr. Raybon's general causation opinions similar to Defendants' argument here. Like Defendants' argument here, Bard's position was based largely on the Court's *Daubert* opinion in *Eghnayem*. *See, Wise*, Case No. 2:12-cv-1378, Dkt. No. 177 (Bard's Motion to Exclude Dr. Raybon). The plaintiffs in *Wise* demonstrated that Dr. Raybon was qualified based upon his clinical experience and observations and therefore should not be limited from offering an opinion as to general causation. *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *15 (S.D.W.Va.2015). As Defendants here fail to acknowledge or address, Bard actually agreed with the plaintiffs in *Wise* that Dr. Raybon was allowed to describe the types of complications associated with its POP kit product, and how they are treated. *Id.* Defendants likewise fail to address the fact that the Court concluded in *Wise* that Dr. Raybon would be allowed to offer general causation opinions that were based upon his observations and clinical experiences and to assess the general causal relationship between pelvic pain and other complications associated with the Bard Avaulta POP kit product at issue there. *Id.* at *16. Defendants offer no basis upon which a different conclusion could or should be reached here; Dr. Raybon should be allowed to testify regarding the general causal relationship between pelvic pain and other complications associated with the Defendants' Prolift and Prolift +M products at issue here, including but not limited to the causal relationship between mesh implantation and nerve damage.

II. Dr. Raybon should be allowed to offer his opinion regarding the adequacy of physician selection and training in light of the consistent "doctor fault" defenses asserted in these cases.

One of the consistent defenses in the pelvic mesh MDL cases generally, including the Ethicon cases, has been that the doctors lacked sufficient skill or experience to properly perform the specific implant procedure, or else that the doctor committed some error (either in the implantation or post-implant treatment) that led to the patient's injury. Particularly when physician error (or physician skill or experience) is asserted as a defense, and when the facts show that Defendants made no effort to determine physician skill and experience before allowing surgeons to implant these products, it is appropriate and necessary for Plaintiffs to be allowed to respond with expert testimony regarding this subject matter. Dr. Raybon's testimony regarding physician training is demonstrably reliable, and it is relevant in light of the "blame the doctor" defenses asserted in many of these cases.

III. Defendant's challenge to Dr. Raybon's opinions that are based upon the factual results of testing and studies that were conducted on the Defendants' products at issue are not the sort of "clinical study" opinions that the Court has excluded in prior cases, and Defendants' motion should fail.

Defendants' challenge to Dr. Raybon's opinions related to the clinical studies is misguided. Defendants cite to prior decisions where the Court has not allowed physicians, including Dr. Raybon, to offer opinions regarding a manufacturer's failure to adequately test their products before releasing them for sale. In those cases, the Court concluded that the proffered physician experts – like Dr. Raybon in the *Wise* case – were not sufficiently qualified to discuss what pre-market testing the manufacturer should or should not have conducted. *See, e.g., Wise v. C.R. Bard, Inc., supra* at *16-*17 (Held: Dr. Raybon not qualified to testify about what testing Bard should or should not have conducted prior to placing the Avaulta on the market). Unlike in *Wise* and other prior cases where the Court has excluded this sort of "clinical

study adequacy" opinion, Dr. Raybon is not offering opinions criticizing the design or process of Defendants' product testing or studies, and he is not offering any opinions about what pre-market testing or studies should (or should not) have been done. Instead, Dr. Raybon cites to the results of product-related studies that were actually performed, and he offers his opinion regarding what these tests demonstrated with respect to the risks associated with Defendants' products (significant rates of serious complications), and also what physicians would have expected to be told and warned by Defendants in light of these studies.[6] These are subjects well within Dr. Raybon's knowledge, education, training and experience as a well-credentialed, Board-certified urogynecologist.

Reliance upon and citation to published literature and objective factual data regarding product-related studies and testing (including Defendants' own testing and studies) in rendering an opinion regarding the risk/benefit profile of the product in question is undeniably an area within Dr. Raybon's qualifications and expertise. *See, e.g., Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, *7 (S.D.W.Va. 2015) (denying defendant's *Daubert* motion seeking to exclude plaintiff's urogynecologist expert regarding risk/benefit profile of defendant's pelvic mesh, stating "Drawing on his clinical experience and review of relevant literature is a sufficiently reliable method of forming the opinion that the risks of polypropylene outweigh the

[6] *See, e.g.*, Raybon Prolift Report, p. 7 ¶ 4 (discussing vaginal implantation study of Gynemesh PS mesh used in Prolift in monkeys, showing higher rates of complications in comparison with other tested materials); *Id.*, p. 8 ¶ 5 (discussing Ethicon cadaver labs demonstrating deformation of Prolift arms upon implantation); *Id.*, p. 16 ¶ 8 (discussing Prolift clinical study that demonstrated 19.6% "painful mesh shrinkage" in Prolift patients); *Id.*, p. 16 ¶ 9 (discussing Ethicon Prolift study by Prolift developer physicians that failed Defendants' own criteria for success, and had a 75.6% adverse event rate; 25.6% serious adverse event rate; 10% "severe" adverse event rate; 50% rate of adverse event requiring treatment; and 66.7% "mesh-related" adverse event rate); *Id.*, pp. 19-22 (discussing unacceptable adverse events demonstrated in clinical studies and testing of Prolift); *See* Raybon Prolift +M Report, p. 15 (discussing internal Prolift +M study demonstrating failure rate of 21.7% failure rate (failing internal success criteria), with incidents of de novo pelvic pain; vaginal wall stiffness; worsening or de novo SUI; and contracted firm mesh at the level of the arms).

benefits."); *Accord*, *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *11 (S.D.W.Va.2015). Likewise, Dr. Raybon is qualified to opine regarding the adequacy of the warnings contained within a medical product's IFU in light of his knowledge and experience, as well as the available information regarding the product-related risks known or available to the Defendants, but not adequately conveyed in the IFU. *See*, *Wise*, *supra* at *14 ("as an experienced urogynecologist, [Dr. Raybon] may testify about the risks he perceives that the [pelvic mesh] product poses to patients and then opine that the [product's] IFU did not convey those risks."). *See also*, *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *11-*13 (S.D.Ill.2011) ("As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions….Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]…and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000)."). In sum, Dr. Raybon's citation of and reference to clinical studies and related internal corporate documents and information in support of his substantive opinions is proper, and Defendants' effort to exclude his opinions is unfounded.

IV. Dr. Raybon should be allowed to offer his opinion on the inadequacy of Defendants' warnings for the Prolift and Prolift +M from his perspective as an expert urogynecologist.

Defendants' challenge to Dr. Raybon's warnings opinions is misguided. Dr. Raybon has reviewed the Prolift and Prolift + M IFUs, Physician Training Materials, and related Ethicon sales and marketing materials, and he has gained extensive hands on training by reading,

reviewing, and advising patients in Instructions for Use (IFU's) from an array of transvaginal mesh devices. (Raybon Prolift Report, pp. 11-19; Raybon Prolift + M Report, pp. 11-15). In fact, Dr. Raybon used the Prolift device, implanting Prolift into over 25 of his own patients, until he stopped using the product after what he considered unacceptable complication rates and inadequate physician training by Defendants. (Raybon Prolift Report, p. 2; Raybon Prolift +M Report, p. 2). Dr. Raybon has removed over 75 Prolift products from his patients. (*Id.*). Dr. Raybon has regularly consulted with pelvic mesh manufacturers for many years regarding the design of their products. (*Id.*). Dr. Raybon is an expert on warnings *from a surgeon's perspective*.

Dr. Raybon does not purport to offer warnings opinions outside of his realm of expertise. His position with regard to the IFU and warnings contained therein is clear: he is offering opinions with regard to the information upon which physicians regularly and reasonably rely, and information regarding the proper implantation technique in order to minimize risks and complications. (Raybon Prolift Report, pp. 11-19; Raybon Prolift + M Report, pp. 11-15). Dr. Raybon is highly-credentialed and experienced and is capable of testifying about physician expectations and what warnings should and/or should not be contained within an IFU so that patients receiving the device can be properly counseled. Likewise, Dr.Raybon is well-qualified to testify about the adequacy of the instructional information provided in the IFU regarding how surgeons were instructed to use the device. In short, Dr. Raybon is qualified to offer opinions regarding expectations of warnings from the standpoint of a physician who implants and removes transvaginal mesh products.

In *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *14 (S.D.W.Va. 2015), the Court allowed Dr. Raybon to opine as to the adequacy of the Defendants' product warnings in the face of a

Daubert challenge similar to that asserted here, concluding that "as an experienced urogynecologist, Dr. Raybon may testify about the risks he perceives that the [defendant's mesh] product poses to patients and then opine that the [product's] IFU did not convey those risks."); *See also, Id.*, p. *5 ("A urogynecologist…is qualified to make this comparison [whether the product's risks were adequately conveyed in the IFU]."). A similar ruling is warranted here.

Defendants' contention that Dr. Raybon is not a warnings expert, has not drafted an IFU, and "does not know the FDA's regulations or regulatory processes relating to warnings" is misplaced. As this Court explained in *Edwards v. Ethicon, Inc.*, "Dr. Blaivas [an expert urogynecologist] need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risk were adequately expressed on the TVT-O's IFU." *Edwards*, 2014 WL 3361923 at *13. Furthermore, an expert need not have drafted the IFU to opine on its adequacy. *Huskey v. Ethicon, Inc.*, 2014 WL 3362264 at *5 (2:12-cv-05201 [Dkt. 271] S.D.W.V. July 8, 2014); *See also, Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501, 560-561 (S.D.W.Va.2014).

In *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *11-*13 (S.D.Ill.2011), the drug manufacturer defendant argued that the plaintiffs' proffered experts, both Obstetrician-Gynecologists, were not qualified to offer opinions regarding the adequacy of its labeling, in part because they had no FDA regulatory expertise. The court in *In re Yasmin* rejected this argument, and held instructively as follows:

> As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]…and to compare that knowledge with what was provided in the text of

> labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualfied to render an opinion as to the drug label's completeness and accurateness. *See id*....
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> Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is left to the trier of fact's determination.[7]

As Dr. Raybon explains in his Report, "[i]n order to make an informed decision as to whether to use a particular product in a given patient, a reasonable physician would expect a medical device company to provide relevant information known to the company that could impact the physician's decision to use that product," and "[f]ailure of the company to provide relevant information in its possession bearing on the potential safety of a product prevents physicians from making an intelligent decision regarding whether to implant the product," and "also prevents physicians from properly counseling patients in considering whether to consent to surgery for permanent implantation of the medical device." (Raybon Prolift Report, p. 12; Raybon Prolift +M Report, p. 12). Dr. Raybon's opinions regarding the completeness and accuracy of Defendants' IFU's are essential to this case and will aid the jury in evaluating the

[7] The same holding with respect to the Plaintiffs other proffered OB-GYN expert in the *Yaz* MDL (Anthony Disciullo) – based on his extensive clinical experience and review of peer-reviewed literature and company documents, he was qualified to offer opinions as to the adequacy of the drug warning label, and his opinions were reliable. *See also Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 702 (W.D.N.C. 2003) (citing *In re: Diet* Drug MDL PTO 1332, where the MDL court concluded physicians are "'qualified to render an opinion as to the labels' completeness, accuracy, and . . . the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits . . . are or were at the time the labeling was published.'…"); *Accord, Burton v. Wyeth-Ayerst Labs. Div. of Amer. Home Prods. Corp.*, 513 F.Supp.2d 708, 712 (N.D.Tex.2007); *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 556 (S.D.N.Y.2004) ("Pursuant to the defendants' concession [in light of *In re: Diet Drugs*], and subject to relevance rulings to be made by the trial courts, these [physician expert] witnesses are not precluded from offering otherwise admissible testimony as to the accuracy of the Rezulin label."); *In re Baycol Prods. Litig.*, 532 F.Supp.2d 1029, 1063-64 (D.Minn.2007) (citing *In re: Diet Drugs* opinion in denying defense *Daubert* motion to exclude physician expert opinion regarding drug labeling, stating "The Court agrees that [the plaintiffs' physician expert] is qualified to render an opinion regarding the completeness or accuracy of the Baycol label based on his knowledge of the risks of Baycol and his own clinical experience.").

adequacy of the document that provides one basis for the physician's risk/benefit analysis and ultimately the information that is conveyed (or not conveyed) to the patient. *See Edwards*, 2014 WL 3361923 at *13. Defendants' challenges to Dr. Raybon's opinions on warnings and information contained within the Prolift and Prolift +M IFU's should be denied.

V. Defendants' attempt to limit Dr. Raybon's opinions regarding certain features that would constitute safer feasible alternatives to the Prolift and Prolift +M design is factually unfounded, and should be denied.

Defendants' criticism of Dr. Raybon's opinions regarding feasible alternative features of the Prolift and Prolift +M designs that would have made the devices safer amounts to little more than a disagreement with his opinions. This is not a valid basis for a *Daubert* challenge. The Court has previously rejected a *Daubert* challenge to Dr. Raybon's qualifications to opine on the design of an multi-armed, polypropylene pelvic organ prolapse mesh kit device. *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *14-*15 (S.D.W.Va. 2015).

For example, Ethicon challenges Dr. Raybon's opinion that polyvinylidene fluoride (PVDF) was a safer feasible alternative material to polypropylene, pointing to Dr. Raybon's testimony that he has not reviewed published literature showing that PVDF was safer and more effective at treating pelvic organ prolapse than polypropylene. (Defendants' Brief, p. 13). There is no such literature because there is no PVDF pelvic organ prolapse product (likely Plaintiffs submit, because PVDF is more expensive than polypropylene). Dr. Raybon cites to a volume of internal Ethicon corporate documents dating back decades that consistently recognize the safety advantages of PVDF, and specifically PVDF versus polypropylene. (Raybon Prolift Report, p. 13 and footnote 15; p. 22 ¶ E and footnote 48).[8] Defendants' contention that Dr. Raybon testified

[8] HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding "dog" study) – "I recall the long-term dog study did show some 'fibrillation' of PROLENE suture where none was observed for PRONOVA [PVDF] suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain

that his opinion that a POP repair mesh without arms is nothing more than an "interesting concept" (Defendants' Brief, p. 14) is equally groundless. Non-armed mesh devices (or sheet mesh) have been sold for POP repair for years, and in fact, Dr. Raybon has implanted these products using the sacrocolpopexy procedure – the recognized gold standard for POP repair – for years, and he continues to do so. (*See, e.g.*, Raybon depo., 25:21-28:22; 48:21-54:10). Defendants' challenge to Dr. Raybon's safer alternative design opinions are factually baseless, and its motion should be denied.

VI. Defendants' challenge to Dr. Raybon's opinions regarding infection are case-specific, and should be reserved for the trial judge in cases where Dr. Raybon is expected to testify when these cases are remanded for trial.

Defendants urge that Dr. Raybon should not be allowed to offer general causation opinions regarding infection in cases where infection is not at issue. However, Defendants at

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discussing literature about polypropylene degradation) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard."); ETH.MESH.14445346 (1/17/12 PowerPoint), Slide 11 (comparing Polypropylene to PVDF) – "PP – Stress cracking after 2 years of implantation [citing Mary article from 1998]… PP – In vivo degradation of PP [citing Clave article from 2009]."); ETH.MESH.09888188 (10/15/92 internal study report) – "Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking"; ETH.MESH.05644809 (8/2/01 internal notes) – "Advantages of Pronova • 50% reduced granuloma (Aachen group) • high inertness (like Teflon) • durability • reduced bending stiffness (better flexibility) • elasticity (fiber elasticity contributing 25% to mesh elasticity, rest by construction) • higher purity (only a blend)"; ETH.MESH.05588125 (7/6/07 internal email) – Dr. Dieter Engel: "Pronova has a reduced foreign body reaction compared to Prolene, as shown in several animal studies, and will improve the perceived biocompatibility of our mesh"; ETH.MESH.05878699 (9/13/07 internal study report) – Prof. Klosterhalfen: "Pronova [compared to Prolene] indicates a superior biocompatibility in the crucial early stage of wound healing within the first weeks"; ETH.MESH.15377374 (8/12/09 internal communication to a supplier) – "…PVDF polymers showed acceptable and often improved performance as compared to PP mesh devices. We have previously shared the preclinical biocompatibility studies for PRONOVA suture (report dated June 1998). Similar findings would be expected for a mesh device made from PRONOVA blend materials"; ETH.MESH.03722384 (9/16/09 internal e-mail) Dr. Thomas Divilio: "We're seeing a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction…Might be better off working with something that is less reactive, like PVDF"; ETH.MESH.00857704 (2/12/09 internal e-mail regarding future mesh design advantages) – "If we use PRONOVA a more elastic fiber which shows less degradation than PP. Better, longer function of Implant."

least implicitly concede that their argument would not apply in cases where infection is involved. This is an issue best addressed by way of motion in limine by the trial judge upon remand.

VII. Dr. Raybon does not intend to offer any opinions regarding FDA "regulatory requirements" or any "FDA opinions, but if FDA evidence is not excluded at trial by the trial court judge upon remand, Dr. Raybon should be allowed to testify regarding the indisputable facts of the regulatory history of the Prolift products.

Contrary to Defendants' characterization, Dr. Raybon has not offered any expert opinion regarding the FDA or its regulatory processes. Throughout the course of this litigation, Defendants have fought vehemently to be allowed to introduce evidence of the FDA's regulatory processes. The Court has correctly excluded such evidence to date in these cases. *See, e.g., In re C.R. Bard, Inc. MDL No. 2187 Pelvic Repair Sys. Prods. Liab. Litig.* (*Cisson v. C.R. Bard, Inc.*), 810 F.3d 913, 919-23 (4th Cir.2016) (evidence regarding 510(k) clearance and related FDA evidence of POP kit device properly excluded). As Plaintiffs have consistently shown, and the Court has repeatedly and properly held, this evidence has no place in this pelvic mesh litigation for a variety of reasons. However, in the event Defendants were allowed by any trial judge on remand to introduce any FDA-related evidence, they cannot simultaneously prevent the jury from learning the facts about the FDA regulatory history of the Prolift product. That Prolift was sold and implanted for years without 510(k) clearance or permission is not an opinion; it is an undeniable fact. These facts inform and support Dr. Raybon's opinions regarding the adequacy of Defendants' warnings, and is the sort of information that doctors and patients would expect to be told by a medical device seller. Likewise, the fact that the FDA has determined that the Prolift devices have not been shown to be safe and effective, and that the products were removed from the market in response to an FDA 522 Order are not matters of Dr. Raybon's opinion, but are matters of fact. These facts bear directly on the risk/benefit design defect analysis.

For example, as the Court is well aware, the pelvic mesh defendants in these MDLs (including these Defendants) have argued extensively that the FDA reviews a 510(k) device to determine its safety and efficacy, and therefore the FDA's 510(k) clearance of their products is at least "some evidence" that the products were safe and effective. That argument is meritless, as has been established. However, if that is the argument Defendants intend to make (and if they were to be allowed to do so), then surely the fact that Defendants knowingly circumvented this process in bringing the Prolift to market would be a permissible subject of expert testimony. Likewise, the fact that the FDA has, in fact, actually reviewed these products, and specifically concluded that there is no demonstrable evidence of safety or efficacy (and the products have been removed from the market as a result) is "fair game" for expert consideration. In short, if Defendants were successful in persuading any trial judge to allow in FDA evidence in any of these cases upon remand, Defendants cannot avoid the truth. The items addressed in Defendants' motion are facts, not opinions; as such, Defendants' *Daubert* motion should be denied.[9]

VIII. Dr. Raybon will not offer opinions regarding Ethicon's "state of mind, knowledge, motives, or intentions," and has not and he does not intend to provide any "narrative review of corporate documents."

Plaintiffs' recognize that the Court will disallow any expert opinions that go to Defendants' "state of mind, knowledge, motives, or intention," and Plaintiffs do not intend to have Dr. Raybon offer any such opinions at trial. *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *13 (S.D.W.Va.2015).[10]

[9] This self-serving attempt to "have it both ways" is one of the main reasons this Court has excluded FDA regulatory evidence in the first instance, as the myriad risks associated with this evidence far outweigh any argued probative value, which is *de minimis*, at best.

[10] The entirety of Defendants' challenge are references in Dr. Raybon's Report to instances where certain facts were "reflected," "recognized," or "acknowledged" in Ethicon's internal documents that Dr. Raybon

Contrary to Defendants' argument in its Brief, Dr. Raybon does not purport to offer any "narrative review" of any documents, but instead cites to and relies upon Defendants' internal documents to inform and support his opinions, much as he did in the *Wise* case. *See*, *Wise*, 2015 WL 521202 at *13 ("[T]hough an expert may not simply narrate corporate documents in front of the jury, he may rely on such information in forming and supporting his opinions…For the most part, Dr. Raybon has properly used Bard's internal documents to develop and reinforce his opinions rather than to narrate Bard's corporate conduct.").

Conclusion

Based on the foregoing argument and citation of authority, Defendants' *Daubert* motion seeking to exclude Dr. Raybon's opinions should be denied.

This 13th day of May, 2016.

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reviewed. (Defendants' Brief, pp. 17-18). Every one of these references in his Report are based squarely on and cite directly to Ethicon's documents. These are not Dr. Raybon's opinions; these are facts. Dr. Raybon is simply pointing to these facts as support for his opinions.

CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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